Re-evaluation Decision RVD2010-08

Butoxypolypropylene Glycol

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Re-evaluation Decision

After a re-evaluation of the insect repellent butoxypolypropylene glycol, Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act*, and Regulations, is granting continued registration of products containing butoxypolypropylene glycol for sale and use in Canada.

An evaluation of available scientific information found that products containing butoxypolypropylene glycol do not present unacceptable risks to human health or the environment when used according to the revised label directions. As a condition of the continued registration of butoxypolypropylene glycol uses, new risk-reduction measures must be included on the labels of all products. No additional data are required at this time.

The regulatory approach for the re-evaluation of butoxypolypropylene glycol was first presented in Proposed Re-evaluation Decision PRVD2010-05, *Butoxypolypropylene glycol*, a consultation document.[1] This Re-evaluation Decision[2] describes this stage of PMRA's regulatory process for the re-evaluation of butoxypolypropylene glycol as well as summarizes the Agency's decision and the reasons for it. No comments were received during the consultation process. This decision is consistent with the proposed re-evaluation decision stated in PRVD2010-05. To comply with this decision, the registrant of products containing butoxypolypropylene glycol will be informed of the specific requirements affecting their product registration(s) and of regulatory options available to them.

What Does Health Canada Consider When Making a Re-evaluation Decision?

The PMRA's pesticide re-evaluation program considers potential risks, as well as value, of pesticide products to ensure they meet modern standards established to protect human health and the environment. Regulatory Directive DIR2001-03, *PMRA Re-evaluation Program*, presents the details of the re-evaluation activities and program structure.

Butoxypolypropylene glycol, one of the active ingredients in the current re-evaluation cycle, has been re-evaluated under Re-evaluation Program 1. This program relies as much as possible on foreign reviews, typically United States Environmental Protection Agency (USEPA) Reregistration Eligibility Decision (RED) documents. For products to be re-evaluated under Program 1, the foreign review must meet the following conditions:

- it covers the main science areas, such as human health and the environment, that are necessary for Canadian regulatory decisions;
- it addresses the active ingredient and the main formulation types registered in Canada; and
- it is relevant to registered Canadian uses.

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

Based on the outcome of foreign reviews and a review of the chemistry of Canadian products, the PMRA has made a regulatory decision and requires appropriate risk-reduction measures for Canadian uses of butoxypolypropylene glycol. In this decision, the PMRA took into account the Canadian use pattern and issues (for example, the federal Toxic Substances Management Policy).

Based on the health and environmental risk assessments published in the 2007 RED, the USEPA concluded that butoxypolypropylene glycol was eligible for reregistration provided risk-reduction measures were adopted. The PMRA compared the American and Canadian use patterns and found the USEPA assessments described in this RED were an adequate basis for the Canadian re-evaluation decision.

For more details on the information presented in this Re-evaluation Decision, please refer to the Science Evaluation in the related Proposed Re-evaluation Decision PRVD2010-05, *Butoxypolypropylene glycol.*

What Is Butoxypolypropylene Glycol?

Butoxypolypropylene glycol is an insect repellent that is used to control flies, mosquitoes and gnats on race horses and on horses/ponies used for recreation. Butoxypolypropylene glycol is applied by wiping-on with a cloth or spraying on with a trigger pump sprayer.

Health Considerations

Can Approved Uses of Butoxypolypropylene Glycol Affect Human Health?

Butoxypolypropylene glycol is unlikely to affect your health when used according to the revised label directions.

People may be exposed to butoxypolypropylene glycol while preparing and/or applying the pesticide to horses and/or ponies, or while handling treated animals (for example, grooming).

The PMRA considers two key factors when assessing health risks: the levels at which no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which exposure is well below levels that cause no effects in animal testing are considered acceptable for continued registration.

The USEPA concluded that butoxypolypropylene glycol was unlikely to affect human health provided that risk-reduction measures were implemented. These conclusions apply to the Canadian situation, and equivalent risk-reduction measures are required.

Environmental Considerations

What Happens When Butoxypolypropylene Glycol Is Introduced Into the Environment?

Butoxypolypropylene glycol is unlikely to affect non-target organisms when used according to the revised label directions.

Birds and aquatic organisms could be exposed to butoxypolypropylene glycol in the environment. Environmental risk is assessed by the risk quotient method—the ratio of the estimated environmental concentration to the relevant effects endpoint of concern. In this screening-level assessment, the resulting risk quotients are compared to corresponding levels of concern. A risk quotient less than the level of concern is considered a negligible risk to non-target organisms, whereas, a risk quotient greater than the level of concern indicates some potential risks of concern.

The USEPA concluded that the reregistration of butoxypolypropylene glycol was acceptable provided risk-reduction measures to further protect the environment were implemented. These conclusions apply to the Canadian situation, and equivalent risk-reduction measures are required.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law. As a result of the re-evaluation of butoxypolypropylene glycol, the PMRA is requiring further risk-reduction measures for product labels.

Human Health

- Additional advisory label statements to reduce user and bystander exposure
- Clarification of the statement regarding the use of treated animals for food/feed

Environment

- Additional advisory label statements to reduce potential surface water contamination

Other Information

Any person may file a notice of objection[3] regarding this decision on butoxypolypropylene glycol within 60 days from the date of publication of this Re-evaluation Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the PMRA's website (Request a Reconsideration of Decision, www.hc-sc.gc.ca/cps-spc/pest/part/protect-proteger/publi-regist/index-eng.php#rrd), or contact the PMRA's Pest Management Information Service by phone (1-800-267-3615) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

[3] As per subsection 35(1) of the *Pest Control Products Act*.